

## Message Text

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43

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-10 ISO-00 OES-05 EB-07 COME-00

RSC-01 /052 R

66605

DRAFTED BY: DHEW/FDA:JRWEINROTH,M.D.

APPROVED BY: OES/SCI/BMP:MBEAUBIEN

DHEW/OIH:MACODDING

EUR/CE:SGEORGE (INFO)

EUR/NE:CFLOYD (INFO)

EUR/WE:WHMARSH (INFO)

EA/ANP:MMICHAUD (INFO)

ARA/MEX:JKEANE (INFO)

----- 051909

R 031407Z JAN 75

FM SECSTATE WASHDC

TO AMEMBASSY CANBERRA

AMEMBASSY PARIS

AMEMBASSY BONN

AMEMBASSY TOKYO

AMEMBASSY MEXICO

AMEMBASSY LONDON

UNCLAS STATE 000967

E.O. 11652: N/A

TAGS: ETRD, TBIO, AS, JA, MX, XG

SUBJ: RECALL OF MEDICAL DEVICE - MODIFIED ABBOTT BIOCHROMATIC  
ANALYZER

REF: STATE 188542, 8/27/74

1. FDA ADVISES THAT ABBOTT LABORATORIES, DIVISIONAL OFFICES,  
820 MISSION STREET, SOUTH PASADENA, CALIFORNIA 91030, ARE  
RECALLING THE ABBOTT BIOCHROMATIC ANALYZER, MODEL ABA-100  
MODIFIED BY T E "PIGGYBACK MODIFICATION" TO CORRECT ONE OF  
THE PROBLEMS THAT RESULTED IN THE INITIAL RECALL. THE MACHINES  
INVOLVED ARE OF TWO TYPES, ONE MODIFIED IN THE FIELD AND ONE  
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MODIFIED AT THE MANUFACTURER BEFORE IT WAS SHIPPED. THE

MODIFICATION CAUSES A "GREATER THAN" SIGN TO BE INSERTED IN PLACE OF THE FIRST DIGIT (THE EXTREME LEFT HAND NUMERAL) OF THE FOUR-DIGIT ANSWER WHEN AN EXTREMELY HIGH ABSORBANCE IS MEASURED. THE PROBLEM, WHICH OCCURS ONLY ON THE END POINT TEST AND NOT WHEN THE RATE MODE IS USED, CAUSES CERTAIN MIS-PRINTS IN THE FIRST DIGIT OF THE FOUR-DIGIT ANSWER, OR EVEN A DELETION OF THE FIRST DIGIT. THE FIRM HAS DETERMINED THAT WHEN THE PROBLEM OCCURS IT WILL AFFECT ALL ANSWERS FOR THE MULTI-CUVETTE POSITIONS TWO THROUGH ZERO ZERO PRINTED DURING A GIVEN END-POINT DETERMINATION, BY OMITTING THE FIRST DIGIT OF FOUR-DIGIT ANSWERS. THE PRESENT SITUATION NOT ONLY ELIMINATES THE FIRST DIGIT ON GLUTOSE TESTS, BUT ALSO HAS ELIMINATED THE FIRST DIGIT ON ALL END-POINT TESTS THAT HAVE FOUR-DIGIT ANSWERS. THE PROBLEM OCCURS INFREQUENTLY AND AT RANDOM.

2. THE FIRM HAS ISSUED INSTRUCTIONS TO CONSIGNEES NOT TO INSTALL, MODIFIED INSTRUMENTS AND NOT TO FIELD MODIFY INSTRUCTIONS IN CUSTOMER'S HANDS.

3. FOREIGN CONSIGNEES:

AUSTRALIA: ABBOTT AUSTRALASIA, PTY, LTD., CAPTAIN COOK DRIVE,  
KURNELL, N.S.W. 2231, AUSTRALIA

FRANCE: COULTER SCIENTIFIC, S.A., 14 RUE EUGENE-LEGENDRE,  
MARGENCY 95580, ANDILLY, FRANCE

GERMANY: COULTER SCIENTIFIC, GMBH, 415 KREFELD, HULSER STRASSE  
295, WEST GERMANY

JAPAN: DAINABOT RADIOSOTOPE LAB, LTD., 2-8 HATCHOBORI 1-CHOME,  
CHUO-KU, TOKYO 104, JAPAN

MEXICO: LABORATORIOS BIOAUTOMATIZADOS, S.A., TIJUANA, MEXICO  
LABORATORIOS CLINICOS ESPECIALIZADOS, 1004 GONZALITOS,  
MONTERREY, MEXICO

UNITED KINGDOM: COULTER SCIENTIFIC LTD., COLD HARBOUR LANE,  
HAPPENDEN, HERTFORDSHIRE, A.L. 54 U.N.,  
ENGLAND  
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4. POSTS ARE REQUESTED TO CHECK TO ASSURE THAT CONSIGNEES HAVE RECEIVED INSTRUCTIONS RELATIVE TO THE "PIGGYBACK MODIFICATION" AND THAT THEY UNDERSTAND THE PROBLEM INVOLVED. KISSINGER

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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL CARE, EQUIPMENT, RECALL  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 03 JAN 1975  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1975STATE000967  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** DHEW/FDA:JRWEINROTH,M.D.  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Film Number:** D750003-1005  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1975/newtext/t19750179/aaaacrjp.tel  
**Line Count:** 111  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 3  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** 75 STATE 188542, 75 8/27/74  
**Review Action:** RELEASED, APPROVED  
**Review Authority:** buchant0  
**Review Comment:** n/a  
**Review Content Flags:**  
**Review Date:** 07 FEB 2003  
**Review Event:**  
**Review Exemptions:** n/a  
**Review History:** RELEASED <07 FEB 2003 by RicharJA>; APPROVED <29 DEC 2003 by buchant0>  
**Review Markings:**

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EO Systematic Review  
05 JUL 2006

**Review Media Identifier:**  
**Review Referrals:** n/a  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** RECALL OF MEDICAL DEVICE - MODIFIED ABBOTT BIOCHROMATIC ANALYZER  
**TAGS:** ETRD, TBIO, AS, JA, MX, XG  
**To:** CANBERRA MULTIPLE  
**Type:** TE  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006